EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Transparency – Clinical data release/publication at the EMA

Patients' and Consumers' Working Party meeting

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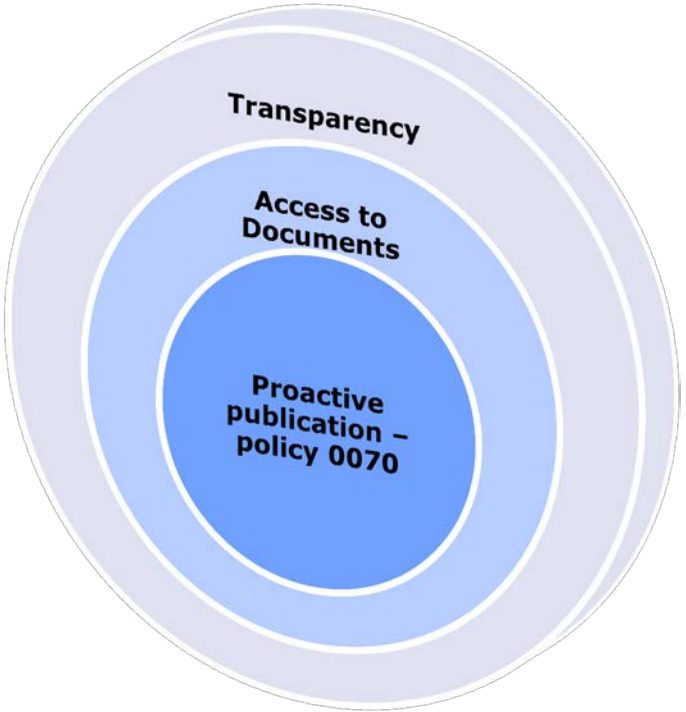
Head of Access to Documents Service

An agency of the European Union

# Outline

- How is transparency translated to the Agency's activities?
- What is access to documents?
- How is access to documents (ATD) handled at the EMA?
- What is Policy 0070?
- How can you help?



# How transparency is translated to the Agency's activities?

- **Publishing** on the EMA website (EPAR, SmPC, RMP summaries, meeting minutes, recommendations from PRAC, agendas, guidelines…)

  Guide to information on human medicines evaluated by EMA published in May 2016
  http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/05/WC500206484.pdf

- Since 2010 **ATD Policy** (Policy 0043)– "reactive" release of any documents upon request
  http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/11/WC500099473.pdf

- **Answering to questions** (Request For Information) asked by stakeholders

  By using a single webform to ask a question or request a document
  http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/landing/ask_ema_landing_page.jsp

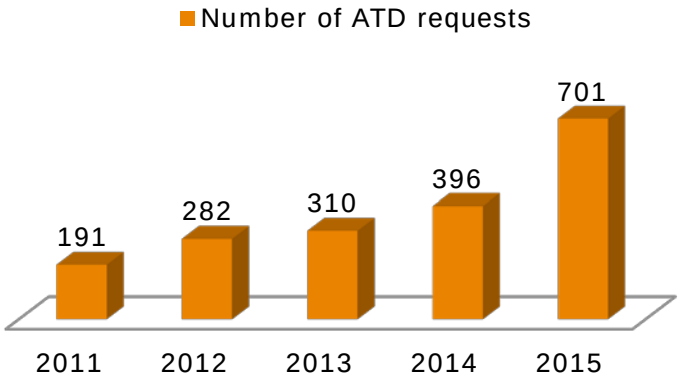
- **Inviting patients** to committee meetings

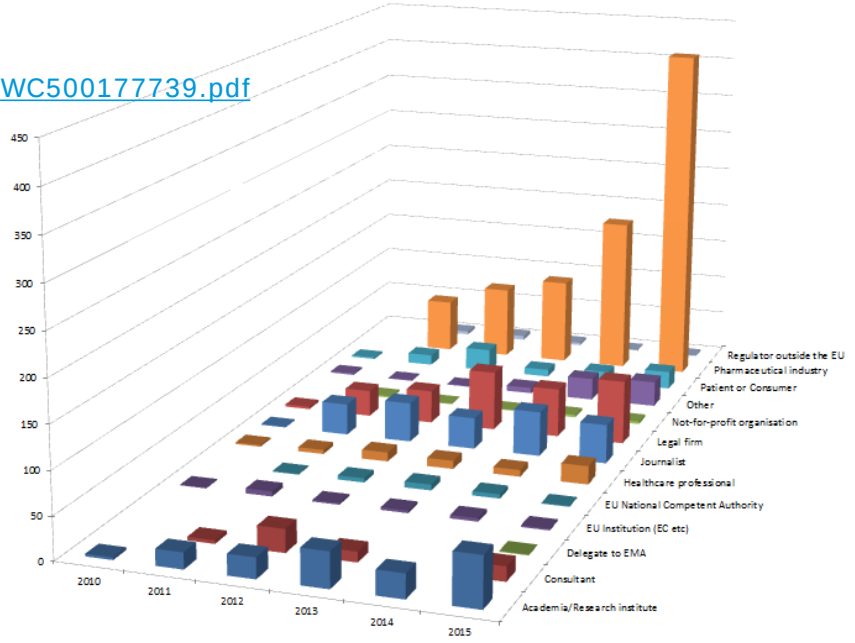

- Since 2014 **Clinical data publication** (Policy 0070) – "proactive" publication of Clinical data
  http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf

# What is access to documents?

- **Legal basis**: Regulation 1049/2001
- **November 2010**: An EMA Policy (Policy 0043)
- **August 2013**: creation of a centralised ATD Service to manage an increasing number of requests
- **August 2014**: Guide on access to unpublished documents

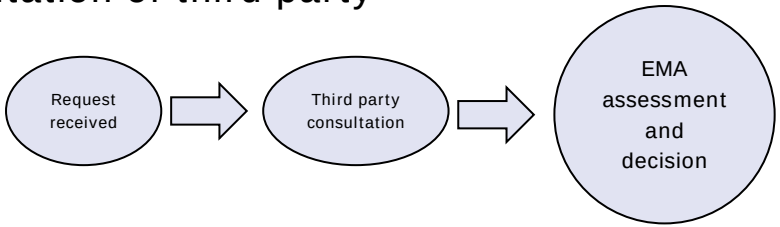
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/11/WC500177739.pdf



# How is access to documents handled at the EMA?

- ATD process – consultation of third party




- What is Commercially 

information (CCI)

Per EMA definition:
Information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information. If in a document information is considered CCI, it may be subject to redaction (blacking out) prior to release to the requester.

# What is Policy 0070?

- The **latest transparency initiative** of the EMA to publish clinical reports that were assessed as part of a Marketing Authorisation Application
  - ⇒ Transparency of assessment
  - ⇒ Development of new knowledge

- Implementation since the adoption in **October 2014**, currently under implementation

- Target date for first publication: **September 2016**

- Guidance have been published, including guidance on what is not CCI

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2016/03/WC500202621.pdf

# We need your help to

- Better **define** what is CCI in Clinical reports
- Better **understand** what patients are looking for when reading Clinical reports
- Which elements of Clinical reports are **essential to patients**

*By completing the short questionnaire below (paper copies distributed)*

| | Very relevant information<br><br>Not to be redacted | Of some relevance/ importance<br><br>Redaction to be considered | Not very relevant information<br><br>Redaction possible if required | I am not familiar with the information contained in this part of the CSR |
|---|---|---|---|---|
| 1, Protocol and design of the study (describing what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study). | | | | |
| 2, Main objectives (end points) of clinical trials | | | | |
| 3, Inclusion and exclusion criteria (who can be included in the trial) | | | | |
| 4, Description of analytical methods that was used to test different physical/chemical properties of the drug | | | | |
| 5, Description of parameters of the drug when passing through within the human body (such as how the body absorbs/distributes/metabolises and eliminates in the body) | | | | |
| 6, Information on study misconduct, including information on the purpose and outcome of audits and inspections carried out during the conduct of clinical trials. | | | | |
| 7, Evaluation of the efficacy of the drug | | | | |
| 8, Safety-related information such as the number of clinical trial participants and adverse reactions (presented in either as a number of events or as description of specific events). | | | | |
| **9, Patient Narratives** | | | | |
| 10, Evaluation of the safety of the drug, including information related to "off label use" or information on adverse events reported in clinical trials conducted in indications subject to on-going development plans (meaning in an indication for which the company has not applied for a marketing authorisation yet). | | | | |

# Thank you for your attention
# &
# your time in completing the questionnaire

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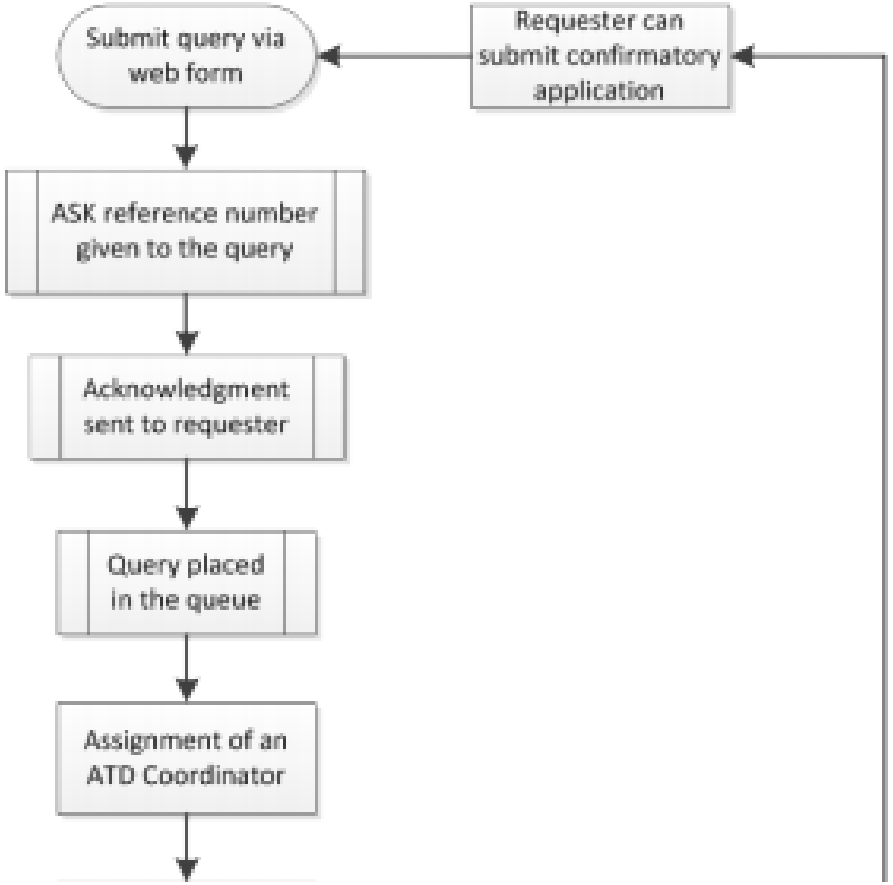
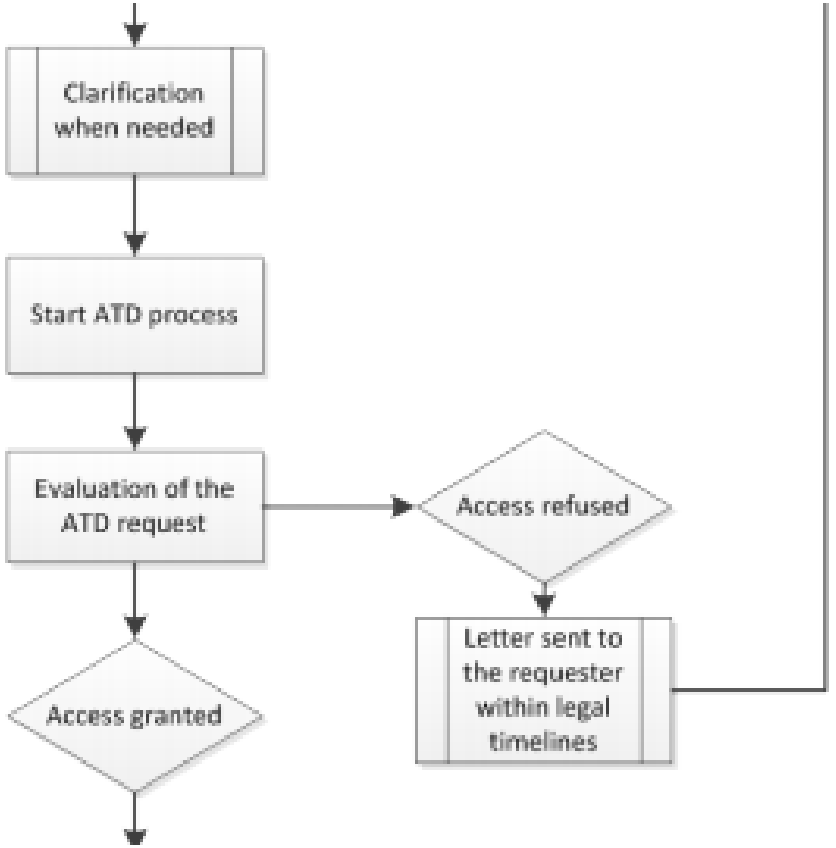
# Back-up Slides

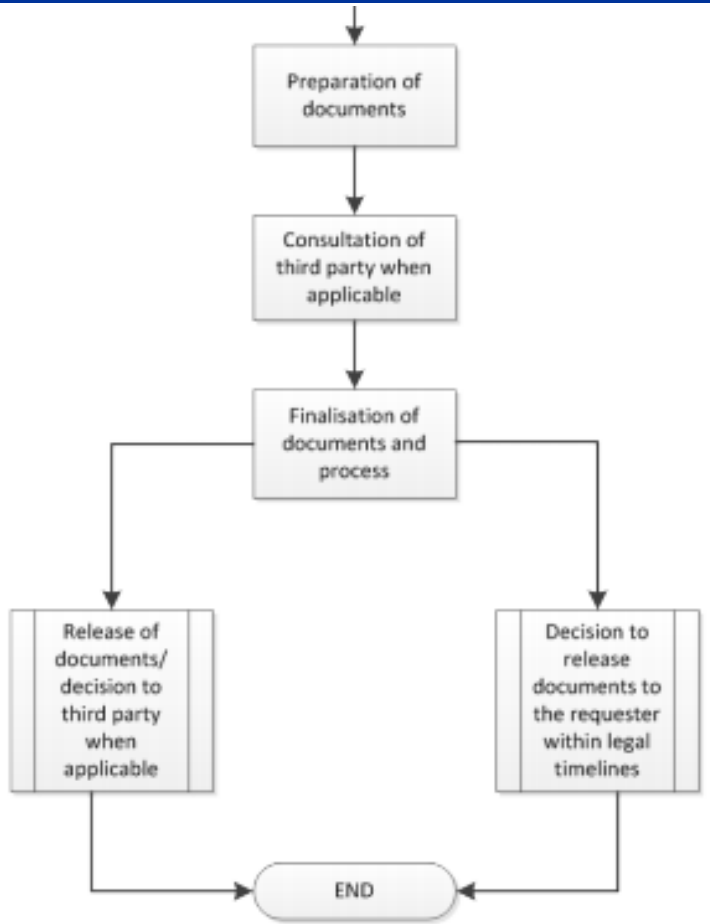
# The ATD process: Redesigned in September 2013



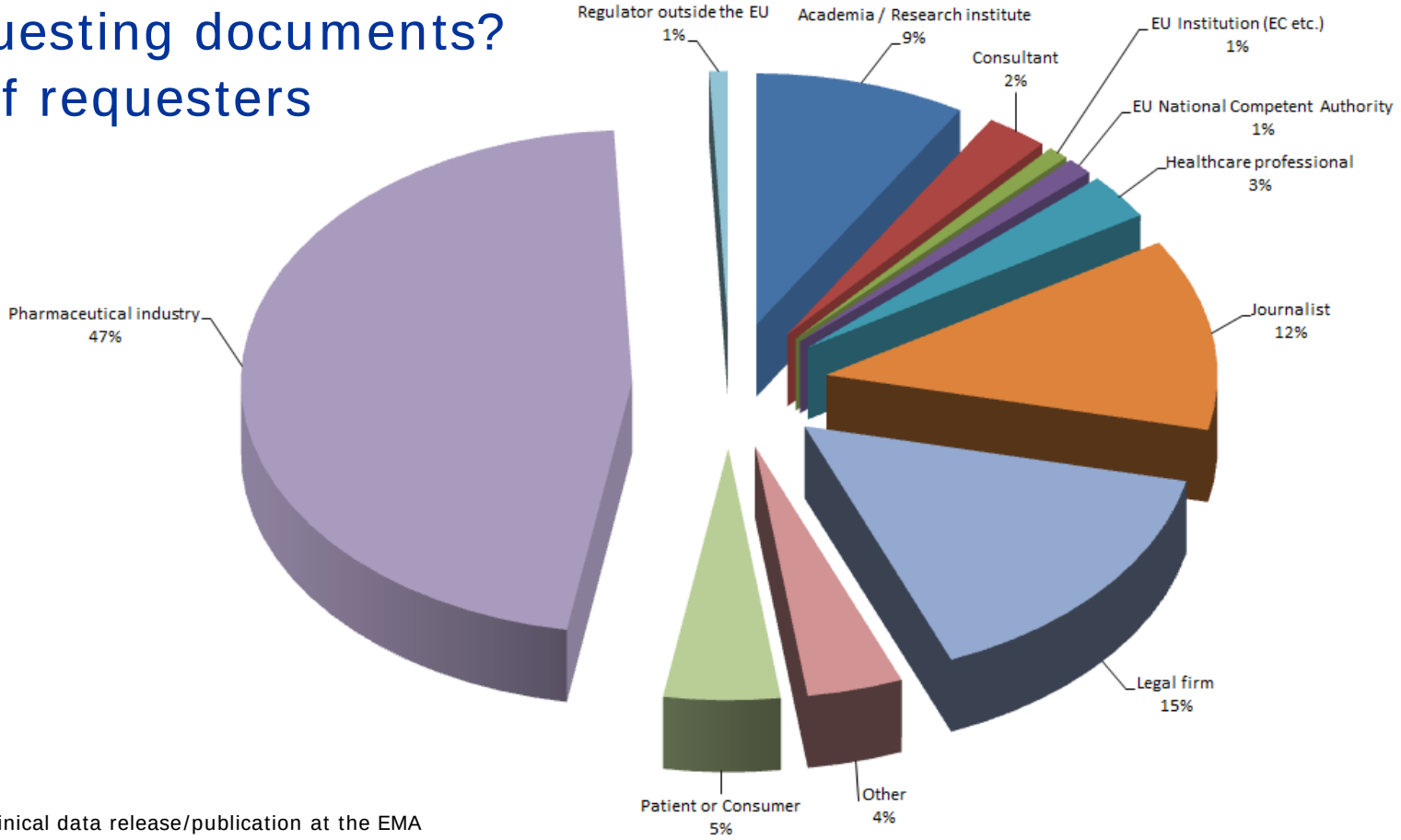
# The ATD process (con't)



# The ATD process (cont'd)



# Who is requesting documents? Affiliation of requesters



# What type of documents are requested? Aug 2013-Aug 2015